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While an increasing number of women at risk for ovarian cancer are being identified through awareness efforts and risk assessment programs, a gap still exists in the known psychological and physical sequelae of preventive surgery options offered to these women. To meet the needs of women seeking information about the effects of prophylactic oophorectomy, this pilot study will provide significant information on the broader quality of life issues and physical changes following surgery. In order to make informed decisions about their choices, women considering prophylactic oophorectomy need scientific data on the hormonal and other physical consequences of surgery, and on the potential alterations in their emotional and social well being. They also need the opportunity to choose from an array of coping strategies to manage their health decisions. Studying multidimensional quality of life issues will contribute to the knowledge base about the short and long-term effects on physical, emotional, cognitive, sexual and social functioning following oophorectomy and will contribute to the development of optimum medical and alternative therapy strategies to deal with post-surgical changes. As important, it will also identify issues and needs faced by women who make the choice not to undergo surgery.

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INTRODUCTION

While an increasing number of women at risk for ovarian cancer are being identified through awareness efforts and risk assessment programs, a gap still exists in the known psychological and physical sequelae of preventive surgery options offered to these women. To meet the needs of women seeking information about the effects of prophylactic oophorectomy and for those who will undergo the procedure, this study will provide significant information on the broader quality of life domains and physiologic changes following surgery. In order to make informed decisions about their choices, women considering prophylactic oophorectomy need scientific data on the hormonal and other physiologic consequences of surgery, and on the potential alterations in their emotional and social well being. They also need the opportunity to choose from an array of coping strategies to manage their health decisions. Ovarian cancer advocacy groups have voiced their support for research that advances not only ovarian cancer prevention and treatment but also quality of life. Studying multidimensional quality of life issues will contribute to the knowledge base about the short and long-term effects on physical, emotional, cognitive, sexual and social functioning following oophorectomy and will contribute to the development of optimum medical and alternative therapy strategies to deal with post-surgical sequelae. As important, it will also identify issues and needs faced by women who make the choice not to undergo surgery.

BODY

The following describes the progress during the past year associated with each task in the Statement of Work.

Task 1: Creation of Participant Advisory Board

We continue with an informal advisory approach, holding consultations by telephone or on a person-to-person basis. A Gynecologic Oncology Clinical Trials Working Group now meets monthly under the direction of Dr. Mitchell Edelson and our staff participates regularly. This forum allows networking and discussion of recruitment strategies. Dr. Marcelle Shapiro, physician and participant in the Family Risk Assessment Program, has offered her services in an advisory capacity. We continue our networking relationship to several local advocacy groups, including the Philadelphia chapter of the National Ovarian Cancer Coalition and The Sandy Rollman Ovarian Cancer Foundation, Inc.

Task 2: Selection of Survey Instruments

There have been no changes in the survey instruments previously approved by the IRB. Outcome variables include physical functioning, menopausal symptoms, body image, sexual functioning, anxiety, depression, and use of pharmaceutical, dietary and alternative therapies. The instruments being used are as follows:

1. The NSABP BCPT Quality of Life Questionnaire. This instrument was used by over 13,000 women in the Tamoxifen prevention trial. It includes the Medical Outcomes Study (MOS) 36-item short form, a generic measure of health-related QOL, the Center for Epidemiologic Studies-Depression Scale, used widely in community epidemiologic studies, the MOS sexual problems scale, and a 43-item symptom

checklist of commonly reported physical and psychologic symptoms, as well as symptoms associated with the menopause, including the domains of vasomotor symptoms, vaginal dryness, sexual functioning, sleep disturbance and cognitive functioning. Sleep patterns and sleep quality may be disrupted by surgical menopause. This questionnaire is collected at all time points.

2. Post-Surgical Expectations Questionnaire. The NSABP BCPT Quality of Life Questionnaire has been modified to assess women's expectations of menopausal symptoms they anticipate experiencing following oophorectomy. It includes an open-ended response format as well as a Likert-type summary scale of symptoms. This questionnaire is only assessed at baseline, prior to surgery.
3. Fallowfield Sexual Activity Questionnaire (SAQ). This tool is a validated measure for describing the sexual functioning of women in terms of activity, pleasure and discomfort. It was developed to investigate the impact of long-term Tamoxifen usage on the sexual functioning of women at high risk of developing breast cancer. This measure is collected at all time points.
4. Self Concept Scale. This 10-item scale assesses the participants' satisfaction with different areas of their body and their overall weight. Persons undergoing oophorectomy may experience an alteration in their perception of their body image, which may affect their psychosocial status and intimate relationships. This scale was developed by Dr. David Cella, (Director, Center on Outcomes Research and Education, Evanston Hospital) through his work with breast cancer patients. It is collected at all time points.
5. Medical/Dietary Supplement Survey. This survey elicits use of hormone replacement therapy, dietary supplements, micronutrients, as well as exercise, yoga, meditation, and other forms of coping strategies. The survey has been piloted among 48 women in the FRAP program for feasibility and ease of administration. Overall, we found that 89% of the women surveyed took some form of dietary supplement. It is collected at all time points.
6. Post-Surgery Satisfaction Questionnaire. Patients' levels of satisfaction with oophorectomy will be assessed using three items rated on a 5-point Likert-type scale. Scores from the three items will be combined to form a composite index of satisfaction. It is collected at all post-surgery time points.
7. Medical Outcomes Survey. This survey will capture information on new medical diagnoses, procedures, and screening exams at the 12-month follow-up time point. It is adapted from our current FRAP annual follow-up questionnaire.

Task 3: Development of a Recruitment Strategy

A recruitment strategy to target *BRCA1* and *BRCA2* mutation carriers who are screened in our FRAP clinic was effective in boosting control group enrollment. The surgery arm now includes 32 women and the control group 18. Compliance with all study time point surveys is relatively consistent. We continue to identify potential candidates through the Family Risk Assessment Program (FRAP) at cancer risk counseling and clinical exam appointments. It is our experience that the decision making process can be quite lengthy for many women who consider prophylactic surgery, which has challenged us in identifying a point in time when the control arm candidates decide against surgery.

Task 4: Creation of Data Entry Screens, Data Editing Program

This task is completed and data entry is a smoothly flowing process. Data is entered promptly and close consultation between the project manager and data entry clerk has served to oversee data editing review. A series of edit checks and quality assurance measures take place on a routine basis whenever data is entered into our bioinformatics system.

Task 5 & 6: Conduct Baseline & Follow-up Surveys

Surveys are sent in packets with an instruction cover letter and postage paid return envelope. The project manager receives an email notice to trigger the sending of packets. Reminder postcards and personal phone calls are made when warranted to alert participants of overdue surveys.

Task 7: Data entry, data analysis

Data entry is up to date. The project manager tracks study accrual and questionnaire completion on a biweekly basis. Interim analysis has yielded the outcomes reported below.

Task 8: Report, manuscript preparation

A HIPAA authorization document was designed and approved by the Authorization subcommittee of our IRB on 3/25/03. The required application for ongoing review by the Research Review and IRB committees at Fox Chase Cancer Center was prepared and approved on 4/25/03. Insufficient data exists at this time for manuscript preparation.

KEY RESEARCH ACCOMPLISHMENTS

- No significant differences in selected sample characteristics including median age, race, education level, marital status and *BRCA* gene mutation status **(See Table 1)**.
- Relative to all Quality of Life measures (NSABP BCPT Quality of Life questionnaire) there were no differences at baseline between the surgery and control groups. At one month, significant differences were seen in percentage of sample experiencing hot flashes ($p=0.02$), in physical functioning ($p=0.03$), in role functioning, physical ($p=0.002$), in social functioning ($p=0.07$), in mental health ($p=0.01$), and in general health perceptions ($p=0.02$) between the surgery and control groups **(See Table 2)**.
- Regarding sexual activity, the majority (80%) of both the surgery and control groups were sexually active at baseline, but at one month there was a statistically significant decrease in sexual activity in the surgery group ($p=0.004$). Further the frequency of sexual activity was less than usual at one month in the surgery group ($p=0.001$) **(See Table 3)**.
- There was no significant difference in self-concept at either baseline or one month between the surgery and control groups **(See Table 4)**.

REPORTABLE OUTCOMES

Table 1 Sample Characteristics		
	Surgery n (%)	**Control n (%)**
Age (median)	45 yrs	42 yrs
Race		
Caucasian	30 (94%)	17 (94%)
Education		
Some College	25 (81%)	15 (88%)
Marital Status		
Married	25 (81%)	11 (65%)
Never Married	3 (10%)	5 (30%)
Divorced	3 (10%)	1 (6%)
***BRCA* Gene mutation status**		
Positive	11 (34%)	7 (39%)
Indeterminate	17 (53%)	6 (33%)
Not tested	4 (13%)	5 (28%)

Table 2 Quality of Life Measures					
	Baseline		**1 month**		
	Surgery	**Control**	**Surgery**	**Control**	
Feelings during the past week	9.3	13.4	7.7	15.9	
Everyday problems during the past 4 weeks	11.0	11.4	11.9	12.4	
% reporting hot flashes	57%	41%	73%	33%	p=0.02
Physical Functioning	91.5	86.2	72.2	86.7	p=0.03
Role Functioning (physical)	81.3	88.2	31.5	76.7	p=0.002
Role Functioning (emotional)	79.2	62.8	84	64.4	
Social Functioning	88	82.4	62	73.3	p=0.07
Bodily Pain	71.3	68.8	50	62.7	
Mental Health	77	68.2	78.9	59.7	p=0.01
Vitality	57.4	46.5	45.6	43	
General health perceptions	75.7	67.9	75.7	64.7	p=0.02

Table 3 Sexual Activity Questionnaire					
	Baseline		One Month		
	Surgery	Control	Surgery	Control	
% engaging in sexual activity	81%	80%	52%	67%	p=0.004
Pleasure score	13.3	12.7	11.1	14	
Pain score	4.3	3.2	4.6	3.3	
Comparison of sexual activity with what is normal for participant	2.1	2.3	2.7	2.1	p=0.001

Table 4 Self Concept Scale				
	Baseline		One Month	
	Surgery	Control	Surgery	Control
Satisfaction with body score	25.7	25.2	26.3	24.6
Importance of breast appearance	2.6	2.8	2.5	2.5
Self concept of weight	1.4	1.6	1.4	1.6

CONCLUSIONS

Data presented here reflects interim analysis of selected measures at the baseline and one-month time points, comparing surgery and control groups. The groups, though small, are well matched and differences have emerged in key areas of quality of life and sexual activity after surgery in the short term. The next year will provide time to collect the remaining six-month and 12-month surveys such that more comprehensive analysis can be performed to determine changes in quality of life over time and between the two groups.

This study will support our efforts to educate women considering prophylactic oophorectomy on the impact of surgery on issues very important to their daily lives, and assist in the development of coping strategies.

REFERENCES

None

APPENDICES

None